K070335

510(k) Summary
for the SIMPLEX Cervical Fixation System

APR 16 2007

This safety and effectiveness summary for the SIMPLEX Cervical Fixation System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

Date Prepared: January 31, 2007

1. **Submitter:**
Pisharodi Surgicals, Inc.
942 Wildrose Lane
Brownsville, TX 78520
Telephone: 956-541-6725

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** SIMPLEX Cervical Fixation System
Common Name: Anterior vertebral body fixation system
Classification Name: Spinal Intervertebral Body Fixation Orthosis per 21 CFR section 888.3060

3. **Predicate or legally marketed devices which are substantially equivalent:**
Radix Cervical Plate – K033951

4. **Description of the device:**
The SIMPLEX Cervical Fixation System consists of plates and screws and is used to build a spinal construct. The purpose of the SIMPLEX Cervical Fixation System is to provide stabilization during the development of a solid spinal fusion. The system is available in a variety of sizes.

Ease of intra-operative handling is enhanced by pre-contouring the plates in two directions to facilitate adaptation to the patient's anatomy and self-tapping uni-cortical screws, which shorten operating time. The screws are available in five lengths. The self-tapping thread of the screws eliminates the need for preliminary tapping.

5. **Intended Use:**
The SIMPLEX Cervical Fixation System is intended for anterior screw fixation of the cervical spine.
Indications for use include:
   - degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
   - spondylolisthesis
   - trauma (i.e., fracture or dislocation)
   - spinal stenosis
   - deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
   - tumor
   - pseudoarthrosis
   - failed previous fusion

Warning:"This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine."

6. **Comparison of the technological characteristics of the device to predicate and legally marketed devices:**
The SIMPLEX Cervical Fixation System is similar in material, plate lengths, ability to angulate and lock the bone screws, pre-contoured plates and indications.

7. **Summary of Nonclincal Tests**
Testing was performed according to ASTM 1717 with results comparable to other cervical plates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pisharodi Surgicals, Inc.
% Mr. J.D. Webb
Authorized Contact Person
1001 Oakwood Blvd.
Round Rock, Texas 78681

APR 16 2007

Re: K070335
Trade/Device Name: SIMPLEX Cervical Fixation System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 16, 2007
Received: March 19, 2007

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070335

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Catherine Brachman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070335